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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-365]

Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2013

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: This notice proposes to adjust the 2013 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, as well as to establish the 2013 aggregate production quotas for three recently temporarily scheduled substances.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before *[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION]*. The electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-365” on all electronic and written correspondence. DEA encourages all comments be submitted electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at <http://www.regulations.gov> for easy reference. Paper comments that duplicate the electronic submission are not necessary and are strongly discouraged as all comments submitted to www.regulations.gov will be posted

for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152; Telephone: (202) 307-7165.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

All comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted

within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA through 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104. DEA published the 2013 established aggregate production quotas for controlled substances in schedules I and II and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the Federal Register (77 FR 59980) on October 1, 2012. That notice stipulated that, as provided for in 21 CFR 1303.13 and 21 CFR 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

Analysis for Proposed Aggregate Production Quotas for Temporarily Scheduled Substances

On May 16, 2013, the Deputy Administrator issued a final order to temporarily schedule three synthetic cannabinoids in schedule I of the CSA: (1-Pentyl-1H-indol-3-yl)(2,2,3,3-

tetramethylcyclopropyl)methanone (UR-144); [1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11); and N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48). See 78 FR 28735. DEA has received applications for registration and quota for these temporarily scheduled substances. In examining the information provided by the applicants, along with other information, DEA finds that there is a current need for these substances. Aggregate production quotas represent those quantities of schedule I and II controlled substances to be manufactured in the United States in 2013 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. As such, pursuant to 21 U.S.C. 826(a), the Deputy Administrator must determine the total quantity and establish production quotas for each of the three temporarily scheduled substances.

In making this determination, the Deputy Administrator has taken into account the criteria that DEA is required to consider in accordance with 21 U.S.C. 826(a) and 21 CFR 1303.11. DEA proposes the aggregate production quotas for these three temporarily scheduled substances by considering: (1) total estimated net disposal of each substance by all manufacturers; (2) estimated trends in the national rate of net disposal; (3) total estimated inventories of the basic class and of all substances manufactured from the class; (4) projected demand for each class as indicated by procurement quotas requested pursuant to 21 CFR 1303.12; and (5) other factors affecting medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Deputy Administrator finds relevant. These quotas do not include imports of controlled substances for use in industrial processes.

Analysis for Proposed Revised 2013 Aggregate Production Quotas and Assessment of Annual Needs

DEA proposes to adjust the established 2013 aggregate production quotas for some schedule I and II controlled substances to be manufactured in the United States in 2013 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes. DEA is not proposing to adjust the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine at this time.

In proposing the adjustment, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. DEA determines whether to propose an adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine by considering: (1) changes in demand for the basic class, changes in the national rate of net disposal for the class, and changes in the rate of net disposal by the registrants holding individual manufacturing quotas for the class; (2) whether any increased demand or changes in the national or individual rates of net disposal are temporary, short term, or long term; (3) whether any increased demand can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota; (4) whether any decreased demand will result in excessive inventory accumulation by all persons registered to handle the class; and (5) other factors affecting the medical, scientific, research, and industrial needs of the United States and lawful export

requirements, as the Deputy Administrator finds relevant.

DEA also considered updated information obtained from 2012 year-end inventories, 2012 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors DEA considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed revised 2013 assessment of annual needs, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407, respectively).

As described in the previously published notice establishing the 2013 aggregate production quotas and assessment of annual needs, DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. See 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, DEA has included in all proposed revised schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting revised established aggregate production quota will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. DEA expects that maintaining this reserve in certain established aggregate

production quotas will mitigate adverse public effects if an unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by DEA. DEA does not anticipate utilizing the reserve in the absence of these circumstances.

The Deputy Administrator, therefore, proposes that the year 2013 aggregate production quotas for the three temporarily scheduled substances be established, and to adjust the 2013 aggregate production quotas for some schedule I and II controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Previously Established 2013 Quotas	Proposed or Proposed Adjusted 2013 Quotas
Temporarily Scheduled Substances		
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	N/A	15 g
[1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	N/A	15 g
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	N/A	15 g
Schedule I		
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g	No change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g	No change
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g	No change
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g	No change
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g	No change
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45 g	No change
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45 g	No change
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g	No change
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45 g	No change
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45 g	No change
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45 g	No change
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45 g	No change

1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45 g	No change
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45 g	No change
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45 g	No change
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	15 g	No change
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	15 g	No change
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	15 g	No change
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	15 g	No change
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	15 g	No change
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	15 g	No change
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	15 g	No change
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g	No change
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g	No change
2,5-Dimethoxyamphetamine	12 g	No change
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	15 g	No change
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	15 g	No change
3,4,5-Trimethoxyamphetamine	12 g	No change
3,4-Methylenedioxyamphetamine (MDA)	30 g	No change
3,4-Methylenedioxymethamphetamine (MDMA)	35 g	50 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g	No change
3,4-Methylenedioxy-N-methylcathinone (methylo)	35 g	No change
3,4-Methylenedioxypyrovalerone (MDPV)	25 g	No change
3-Methylfentanyl	2 g	No change
3-Methylthiofentanyl	2 g	No change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g	No change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12 g	No change
4-Methoxyamphetamine	88 g	No change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12 g	25 g
4-Methylaminorex	12 g	No change
4-Methyl-N-methylcathinone (mephedrone)	25 g	No change
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g	No change
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	53 g	No change
5-Methoxy-3,4-methylenedioxyamphetamine	12 g	No change
5-Methoxy-N,N-diisopropyltryptamine	12 g	No change
5-Methoxy-N,N-dimethyltryptamine	10 g	No change
Acetyl-alpha-methylfentanyl	2 g	No change
Acetyldihydrocodeine	2 g	No change
Acetylmethadol	2 g	No change
Allylprodine	2 g	No change
Alphacetylmethadol	2 g	No change
Alpha-ethyltryptamine	12 g	No change

Alphameprodine	2 g	No change
Alphamethadol	2 g	No change
Alpha-methylfentanyl	2 g	No change
Alpha-methylthiofentanyl	2 g	No change
Alpha-methyltryptamine (AMT)	12 g	No change
Aminorex	12 g	No change
Benzylmorphine	2 g	No change
Betacetylmethadol	2 g	No change
Beta-hydroxy-3-methylfentanyl	2 g	No change
Beta-hydroxyfentanyl	2 g	No change
Betameprodine	2 g	No change
Betamethadol	2 g	No change
Betaprodine	2 g	No change
Bufotenine	3 g	No change
Cathinone	12 g	No change
Codeine-N-oxide	602 g	No change
Desomorphine	5 g	No change
Diethyltryptamine	12 g	No change
Difenoxin	50 g	No change
Dihydromorphine	3,300,000 g	No change
Dimethyltryptamine	18 g	No change
Gamma-hydroxybutyric acid	46,250,000 g	No change
Heroin	25 g	No change
Hydromorphenol	54 g	No change
Hydroxypethidine	2 g	No change
Ibogaine	5 g	No change
Lysergic acid diethylamide (LSD)	30 g	No change
Marihuana	21,000 g	No change
Mescaline	13 g	No change
Methaqualone	10 g	No change
Methcathinone	14 g	No change
Methyldihydromorphine	2 g	No change
Morphine-N-oxide	655 g	No change
N,N-Dimethylamphetamine	12 g	No change
N-Benzylpiperazine	15 g	No change
N-Ethylamphetamine	12 g	No change
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g	No change
Noracymethadol	2 g	No change
Norlevorphanol	52 g	No change
Normethadone	2 g	No change
Normorphine	18 g	No change
Para-fluorofentanyl	2 g	No change

Phenomorphan	2 g	No change
Pholcodine	2 g	No change
Properidine	2 g	No change
Psilocybin	2 g	10 g
Psilocyn	4 g	No change
Tetrahydrocannabinols	491,000 g	No change
Thiofentanyl	2 g	No change
Tilidine	10 g	No change
Trimeperidine	2 g	No change
Schedule II		
1-Phenylcyclohexylamine	3 g	No change
1-Piperdinocyclohexanecarbonitrile	21 g	No change
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000 g	No change
Alfentanil	38,250 g	No change
Alphaprodine	3 g	No change
Amobarbital	9 g	No change
Amphetamine (for conversion)	22,875,000 g	No change
Amphetamine (for sale)	42,625,000 g	47,186,000 g
Carfentanil	6 g	No change
Cocaine	240,000 g	No change
Codeine (for conversion)	81,250,000 g	No change
Codeine (for sale)	49,506,250 g	No change
Dextropropoxyphene	19 g	No change
Dihydrocodeine	250,000 g	No change
Diphenoxylate	750,000 g	No change
Ecgonine	127,500 g	144,000 g
Ethylmorphine	3 g	No change
Fentanyl	2,108,750 g	No change
Glutethimide	3 g	No change
Hydrocodone (for sale)	99,625,000 g	No change
Hydromorphone	5,968,750 g	No change
Isomethadone	5 g	No change
Levo-alphacetylmethadol (LAAM)	4 g	No change
Levomethorphan	6 g	No change
Levorphanol	4,500 g	No change
Lisdexamfetamine	21,000,000 g	No change
Meperidine	6,875,000 g	No change
Meperidine Intermediate-A	6 g	No change
Meperidine Intermediate-B	11 g	No change
Meperidine Intermediate-C	6 g	No change
Metazocine	6 g	No change
Methadone (for sale)	25,000,000 g	33,125,000 g

Methadone Intermediate	32,500,000 g	40,500,000 g
Methamphetamine	3,912,500 g	No change
[987,500 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,863,750 grams for methamphetamine mostly for conversion to a schedule III product; and 61,250 grams for methamphetamine (for sale)]		
Methylphenidate	80,750,000 g	96,750,000 g
Morphine (for conversion)	103,750,000 g	91,250,000 g
Morphine (for sale)	60,250,000 g	No change
Nabilone	25,628 g	No change
Noroxymorphone (for conversion)	9,000,000 g	No change
Noroxymorphone (for sale)	508,750 g	1,262,500 g
Opium (powder)	91,250 g	No change
Opium (tincture)	1,287,500 g	No change
Oripavine	22,750,000 g	No change
Oxycodone (for conversion)	10,250,000 g	No change
Oxycodone (for sale)	131,500,000 g	153,750,000 g
Oxymorphone (for conversion)	18,375,000 g	No change
Oxymorphone (for sale)	6,875,000 g	No change
Pentobarbital	42,500,000 g	No change
Phenazocine	6 g	No change
Phencyclidine	30 g	No change
Phenmetrazine	3 g	No change
Phenylacetone	20,000,000 g	29,628,750 g
Racemethorphan	3 g	No change
Remifentanil	3,750 g	No change
Secobarbital	215,003 g	No change
Sufentanil	6,255 g	No change
Tapentadol	13,750,000 g	No change
Thebaine	145,000,000 g	No change
List I Chemicals		
Ephedrine (for conversion)	15,100,000 g	No change
Ephedrine (for sale)	3,500,000 g	No change
Phenylpropanolamine (for conversion)	25,700,000 g	No change
Phenylpropanolamine (for sale)	6,100,000 g	No change
Pseudoephedrine (for sale)	225,000,000 g	No change

The Deputy Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the

Deputy Administrator may adjust the 2013 aggregate production quotas and assessment of annual needs as needed.

Comments

Pursuant to 21 CFR 1303.11 and 21 CFR1315.11, any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this Notice, the Deputy Administrator may hold a public hearing on one or more issues raised. In the event the Deputy Administrator decides in his sole discretion to hold such a hearing, the Deputy Administrator will publish a notice of any such hearing in the Federal Register. After consideration of any comments and after a hearing, if one is held, the Deputy Administrator will publish in the Federal Register a Final Order establishing any adjustment of 2013 aggregate production quota for each basic class of controlled substance and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

Dated: June 14, 2013

Thomas M. Harrigan
Deputy Administrator

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